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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/748,484 | 12/29/2003 | Darrell C. Conklin | 97-72D1 | 9463 |

7590 04/05/2006

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT PAPER NUMBER

1646

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/748,484

Applicant(s)

CONKLIN ET AL.

Examiner

Prema M. Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amended claim 1 (2/21/2006) and original claim 2 are under consideration by the Examiner.
2. Receipt of applicant's arguments and amendments filed on 2/21/2006 is acknowledged.
3. The following previous objections and rejections are withdrawn in light of applicants amendments filed on 2/21/2006:
 - (i) the objection to the specification;
 - (ii) the rejection of claim 1 as being directed to non-statutory subject matter; and
 - (iii) the rejection of claims 1-2 under 35 USC 112, second paragraph.
4. Applicant's arguments filed on 2/21/2006 have been fully considered and were persuasive in part. The issues remaining are restated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-35 USC § 101/§ 112, first paragraph

6. Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

This rejection is maintained for reasons of record set forth at pages 3-7 of the previous Office action (11/18/2005).

Applicants argue that according to MPEP § 2107 (II) they need provide one credible assertion of specific and substantial utility and that they have provided a credible, specific and substantial utility: Zcyto10 is useful in promoting wound healing. Furthermore, Applicants argue that as stated in the M.P.E.P. § 2107.01(I)(A) a "specific utility" is one where an Applicant "discloses a

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specific biological activity" and "reasonably correlates that activity to a disease condition" and that Applicants have indeed disclosed a "specific and substantial" biological activity for Zcyto10: to promote wound healing because in Example 4 Zcyto10 expression is upregulated in wounded skin. However, contrary to Applicants' arguments, an asserted utility must meet the three-pronged test of being credible, specific and substantial. The office action has never brought into question the credibility of the asserted utility. However, the asserted utility does not satisfy all three prongs. Zcyto10 expression being upregulated in wounded skin does not provide evidence of a specific biological activity and therapeutic utility to treat burns or promote wound healing. Applicants have not demonstrated a nexus between Zcyto10 expression being upregulated in wounded skin and healing of the wound. The skilled artisan would have to conduct significant further research i.e. blocking expression of Zcyto10, to determine if indeed Zcyto10 is involved in wound healing, in order to identify a specific and substantial utility for Zcyto10. In this case the asserted utility is not specific nor is it substantial. Therefore, the asserted utility of using Zcyto10 to treat burns or promote wound healing, fails to satisfy the three-pronged test for utility: credible, specific and substantial, because there is no disclosure in the instant specification suggesting what type of role is played nor what types of wounds involve overexpression of Zcyto10.

It would take significant further research to determine the "role" of Zcyto10 when it is upregulated in wounded skin because there are a diverse group of cytokines, which play a role in modulating local and systemic inflammatory reactions. Some cytokines like IL-4 and IL-10 relieve inflammation while IL-1 enhances inflammation. However, all these cytokines can be said

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to “modulate” or “play a role” in inflammation. Therefore, the assertion that Zcyto10 would be useful in treatment of burns or to promote wound healing is not a specific assertion of utility.

The specification provides no clear nexus between wound healing and any specific change in Zcyto10 expression. Applicants have failed to identify any reasonable use that can be identified as providing a public benefit since significant further research would be required before Zcyto10 could be used in a real-world treatment to promote wound healing. It is true that pharmacological activity is substantial. The issue here is that the mere statement of utility that Zcyto10 would be useful in treatment of burns or to promote wound healing is not specific or substantial. There is no *in vitro* testing to establish a practical utility for Zcyto10. The specification fails to characterize the role of Zcyto10 in wounded skin and therefore the claimed invention lacks utility.

Conclusion

No claim is allowed.

Claims 1-2 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D., J.D.

Primary Examiner

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February 28, 2006